



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 42 CFR part 50 Subpart F and Responsible Prospective Contractors 45 CFR part 94 (OD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Kathy Hancock, Assistant Grants Compliance Officer, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration (OPERA), 6705 Rockledge Drive, Room 3523, Bethesda, MD 20892, or call non-toll-free number (301) 435-1962, or E-mail your request, including your address to: FCOICompliance@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 42 CFR part 50 Subpart F and Responsible Prospective Contractors 45 CFR part 94 OMB# 0925-0417, Expiration Date: 02/2015, EXTENSION, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: This is a request for OMB Approval for an extension of the information collection and recordkeeping requirements contained in the final rule 42 CFR part 50, Subpart F and 45 CFR part 94. The purpose of these

regulations is to promote objectivity in research by requiring institutions to establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.

OMB approval is requested for an extension of 3 years. There are operating costs and/or maintenance costs per response. The total estimated annualized burden hours are 676,130.

Estimated Annualized Burden Hours

Type of Respondent Based on Applicable Section of Regulation	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Reporting				
Initial Reports under 42 CFR 50.605(b)(1) and (b)(3) or 45 CFR 94.5(b)(1) and (b)(3) from Awardee Institutions	950	1	2	1,900
Subsequent Reports under 42 CFR 50.605(a)(3)(iii) and (b)(2) or 45 CFR 94.5(a)(iii) and (b)(2) from Awardee Institutions	50	1	2	100

Mitigation Reports under 45 CFR 94.5(a)(3)(iii) and (b)(2) from Awardee Institutions	5	1	2	10
Annual Report under 42 CFR 50.605(b)(4) or 45 CFR 94.5(b)(4) from Awardee Institution	950	1	1	950
Subsequent Reports under 42 CFR 60.606(a) or 45 CFR 94.6 (a) from Awardee Institution	20	1	10	200
Record Keeping				
Under 42 CFR 50.604(i) or 45 CFR 94.4(i) from Awardee Institutions	2,000	1	4	8,000
Disclosure				
Under 42 CFR 50.604(a) or 45 CFR 94.4(a) for Investigators	3,000	1	81	243,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Investigators	38,000	1	30/60	19,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Institutions	2,000	1	6	12,000
Under 42 CFR 50.604(c)(1) or 45 CFR 94(c)(1) from Sub-recipients	500	1	1	500
Under 42 CFR 50.604(d) or 45 CFR 94.4(d) Institutions	3,000	1	1	3,000

Under 42 CFR 50.604(e)(1) or 45 CFR 94.4(e)(1) for Investigators	38,000	1	4	152,000
Under 42 CFR 50.604(e)(2) or 45 CFR 94.4(e)(2) for Investigators	38,000	1	1	38,000
Under 42 CFR 50.604(e)(3) or 45 CFR 94.4(e)(3) for Investigators	950	1	30/60	475
Under 42 CFR 50.604(f) or 45 CFR 94.4(f) for Institutions	2,000	1	1	2,000
Under 42 CFR 50.605(a)(1) or 45 CFR 94.5(a)(1) for Institutions	2,000	1	82	164,000
Under 42 CFR 50.605(a)(3) or 45 CFR 94.5(a)(3) for Institutions	500	1	3	1,500
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i) for Institutions	50	1	80	4,000
Under 42 CFR 50.605 (a)(3)(ii) or 45 CFR 94.5 (a)(3)(ii) for Institutions	50	1	80	4,000
Under 42 CFR 50.605 (a)(3)(iii) or 45 CFR 94.5 (a)(3)(iii) for Institutions	50	1	1	50
Under 42 CFR 50.605(a)(4) or 45 CFR 94.5(a)(4) for Institutions	950	1	12	11,400

Under 42 CFR 50.605(a)(5) or 45 CFR 94.5(a)(5) for Institutions	2,000	1	5	10,000
Under 42 CFR 50.606(c) or 45 CFR 94.6(c) for Institutions	50	1	30/60	45

Dated: December 17, 2014.

Lawrence Tabak,

Deputy Director,

Office of the Director, NIH.

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